

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) 09 MAY 2005	
FOR FURTHER ACTION See paragraph 2 below	
Applicant's or agent's file reference. 3115.00067	
International application No. PCT/US04/25518	International filing date (day/month/year) 05 August 2004 (05.08.2004)
Priority date (day/month/year) 08 August 2003 (08.08.2003)	
International Patent Classification (IPC) or both national classification and IPC IPC(7): C12N 5/00 and US Cl: 435/325, 375, 377; 424/85.2, 85.5, 85.1, 85.4; 514/2	
Applicant IRx THERAPEUTICS, INC.	

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

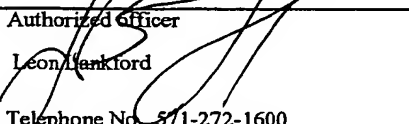
2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized Officer  Leon Hankford Telephone No. 571-272-1600
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International application No.

PCT/US04/25518

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-32</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-32</u>	NO
Industrial applicability (IA)	Claims <u>1-32</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-32 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Claims 1-32 lack an inventive step under PCT Article 33(3) as being obvious over Hadden et al (5632983).

Hadden teaches a treatment of immune problems using a therapeutic NCM (a composition which contains 200-500 units of IL-2 (col 6)- a compound notoriously old and well known for the treatment of cancer). The composition contains all of applicant's limitations with the exception that it does not contain CY or INDO. The invention lacks an inventive step because it would have been obvious to add CY or INDO to the therapeutic composition of the patent because the composition is intended to modulate the immune system of a patient and CY and INDO (or other NSAIDs) are notoriously old and well known for their use in chemotherapeutic immunocompositions or anticancer compositions.

Claim 30 lacks novelty under PCT Article 33(2) as being anticipated by Hadden.

Hadden teaches a therapeutic NCM which contains all of applicant's limitations thus anticipating the claim.